

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
31 March 2005 (31.03.2005)

PCT

(10) International Publication Number
WO 2005/027880 A1

(51) International Patent Classification⁷: **A61K 9/48**,
31/4439

[IN/IN]; Natco Pharma Limited, Natco House, Road No.2,
Banjara Hills, Hyderabad 500 033, Andhra Pradesh (IN).

(21) International Application Number:
PCT/IN2003/000323

(22) International Filing Date:
25 September 2003 (25.09.2003)

(25) Filing Language: English

(26) Publication Language: English

(71) Applicant (*for all designated States except US*): **NATCO PHARMA LIMITED** [IN/IN]; Regd office: "NATCO HOUSE", Road No.2, Banjara Hills, Hyderabad 500 033, Andhra Pradesh (IN).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **PODILI, Khadga-pathi** [IN/IN]; Natco Pharma Limited, Natco House, Road No.2, Banjara Hills, Hyderabad 500 033, Andhra Pradesh (IN). **VENKALAH CHOWDARY, Nannapaneni**

(54) Title: ENTERIC SOFT GELATIN CAPSULE CONTAINING ESOMEPRAZOLE AND METHOD OF PREPARATION

(57) Abstract: The present invention relates to an improved pharmaceutical composition, in the form of a soft gel capsule resistant to digestive juice. The composition of the present invention is made up of gelatin and an enteric polymer in the form of free acid or its salt, containing used in the treatment of duodenal ulcers, solubilised and / or suspended in a liquid or semisolid medium, comprising the enantiomers of omeprazole such as esomeprazole or rabeprazole or other enantiomers of omeprazole or its salts or derivatives or their mixtures, a hydrophobic carrier, an alkaline inert reacting material and a surface active agent and / or a solubilising agent wherein the resulting capsules being insoluble in aqueous medium up to a pH of 5.5 but quickly dissolving above pH of 6.0. The present invention also relates to a process of preparing the above said pharmaceutical composition.



WO 2005/027880 A1